K110268

MAY 3 1 2011

1.1 Submitter Information:

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1.2 Name of Device

Trade name: ForceTriad™ Electrosurgical Generator

Common/Classification name: Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400)

Product Code: GEI

Additional Classification name: Endoscopic electrosurgical unit and accessories. (21 CFR 876.4300)

Subsequent Product Code: KNS

1.3 Predicate Devices

This version of the ForceTriad™ Electrosurgical Generator is substantially equivalent to the ForceTriad™ Electrosurgical Generators cleared under K051644 and K070162. The purpose of this submission is to notify FDA of the software updates to the ForceTriad™ Electrosurgical Generator that activates a bipolar resection feature. This mode is substantially equivalent to the resectoscope use feature on the ERBE™ VIO 300 D generator (K060484, including accessories), the Karl Storz Endocopy Autocon II 400 Electrosurgical Generator (K062464), and the Gyrus ACMI PlasmaKinetic™ SuperPulse Generator (K100816). This feature is compatible with the Karl Storz (KSEA) Bipolar Electrotome resectoscope (K061541) and the newly designed adaptor cable (with predicate cables from Sutter Electrosurgical Cables (K073450)) that connects the ForceTriad™ Electrosurgical Generator to the Karl Storz bipolar resectoscope.

The intended use for the ForceTriad Electrosurgical Generator remains the same as the previous ForceTriad generators. The change to the indications for use includes definitions for "cut" and "coagulating" that are recognized as ways to further describe and clarify the meaning of "cut (resecting, dividing, or separating)" and "coagulating (hemostasis, coagulating, desiccating, or ablating)." Additionally, the proposed indications for use statement includes the clause from the Wolf resectoscope predicate (K062720) "for endoscopically controlled removal of tissue using 0.9% NaCl solution (saline) as the irrigation medium."

1.4 Device Description

The ForceTriad™ Electrosurgical Generator is a full-featured electrosurgical generator with monopolar, bipolar, and LigaSure™ vessel sealing output modes. The generator is an electrically isolated, microcontroller-based device, incorporating closed-loop control for all output modes implemented in the microcontroller firmware. The generator incorporates Instant

Response™ technology to constantly measure the electrical impedance of the tissue and instantaneously adjust the generator output to maintain the desired power.

The generator is used with a selection of electrosurgical instruments designed for use with the ForceTriad and the LigaSure Vessel Sealing generator. All of the LigaSure instruments are capable of sealing vessels up to, and including, 7mm, and tissue bundles as large as can fit in the jaws of each instrument. When a LigaSure instrument is applied to a vessel or tissue bundle and RF energy is applied, the collagen and elastin in the tissues are reformed by heat and pressure to fuse vessel walls, thereby forming a permanent seal. The microprocessor in the generator monitors the tissue properties, stops the application of energy, and allows a brief period of cooling before indicating that the seal cycle is complete.

No changes are being made to the design, operation, or intended use of any of the current system except the software modifications to create the Bipolar Resection modes and to allow the ForceTriad to output system data to a computer. The subject of this 510(k) notification is in regards to the addition of specific definitions for "cut" and "coagulating" and the addition to the indications statement of a bipolar resection function for use with resectoscopes "for endoscopically controlled removal of tissue using 0.9% NaCl solution (saline) as the irrigation medium" and the hardware and software associated with the activation of this feature.

1.5 Intended Use

The ForceTriad is a full-featured electrosurgical generator intended for open and laparoscopic surgical procedures where the surgeon requires electrosurgical cutting (resecting, dividing, or separating), coagulation (hemostasis, coagulating, or desiccating), or vessel sealing (sealing or fusing). The generator is intended for use in general, laparoscopic, and gynecologic surgical procedures where vessel sealing (ligation of vessels, pulmonary vasculature, or lymph vessels), is desired. The system creates a vessel ligation (seal) by the application of bipolar electrosurgical RF energy (coagulation) to vessels interposed between the jaws of the device. The generator can also be used with standard bipolar devices where bipolar cutting or coagulation is desired or with compatible resectoscopes for endoscopically controlled removal (resection) or coagulation of tissue using 0.9% NaCl solution (saline) as the irrigation medium.

The indications for use include general (including urologic, thoracic, plastic, and reconstructive), laparoscopic, and gynecological procedures where electrosurgical cutting and coagulation of tissue, and sealing (fusion) of vessels, including pulmonary vessels, and tissue bundles is performed, including such procedures as bowel resections, hysterectomies (both vaginal and abdominal), laparoscopic cholesystectomies, laparoscopically assisted vaginal hysterectomies, gall bladder procedures, Nissen fundoplication, adhesiolysis, oophorectomy, etc. The devices can be used on vessels (arteries, veins, pulmonary arteries, pulmonary veins, lymph) up to 7mm and bundles as large as will fit in the jaws of the instruments.

The LigaSure tissue fusion function has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures. Do not use this function for these procedures.

1.6 Summary of Technological Characteristics

The technological characteristics of the ForceTriad generator have not changed, except additional software updates to allow additional instruments to be recognized by the ForceTriad™ Electrosurgical Generator. These instruments include an adaptor cable to allow a third party resectoscope to connect to the ForceTriad™, a two (2) pedal footswitch specific to bipolar resection for CUT and COAG effect, and an activation kit that allows users to activate

the bipolar resection feature on their ForceTriad Electrosurgical Generator. This software change includes a user interface for the ForceTriad generator to work with third party resectoscopes in a bipolar mode. Software modifications have been implemented that allow adaptor cables to be recognized by the ForceTriad™ generator, through the LigaSure 2 port, for the connection to a third party bipolar resectoscope. A new graphical user interface has been created for the newly available bipolar resection mode in a saline environment. There are six (6) effect settings (power modes) for both the bipolar CUT and COAG effect modes, with an increased bipolar power output of up to 375 Watts.

An updated User Guide has been provided for the generator, as well as Instructions for Use for the bipolar resection Activation Kit, bipolar resection adaptor cord, and the bipolar resection footswitch. This bipolar resection mode will be available starting in software version 3.30 and higher. For generators in the field that do not have software version 3.30 or higher, a software update is available through Valleylab Exchange.

1.7 Preclinical Performance

Software validation was conducted to qualify the software changes. Bench testing using a pork model (to simulate prostate) and live porcine model using kidney (for hemostasis) was also conducted. In addition testing required by the revisions of the relevant safety standards was conducted. Results were acceptable.

1.8 Clinical Performance

This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

1.9 Conclusion

Based on the information provided, Covidien concludes that the modified device is substantially equivalent to the predicate devices. The software modifications made to the ForceTriad™ detailed in this Traditional 510(k) have not introduced any new questions of Safety and Efficacy. The new software was developed and tested in accordance with the Design Control regulations and internal procedures. Testing found that the software met acceptance criteria. The testing results at the system and individual accessories levels have met the pass–fail criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY 3 1 2011

Re: K110268
Trade/Device Name: ForceTriad Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulation Name: GEI
Regulatory Class: Class II
Dated: May 24, 2011
Received: May 25, 2011

Dear Mr. Henton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

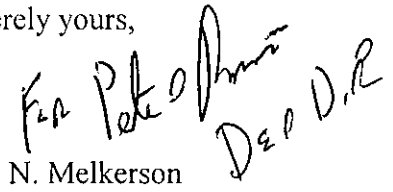
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K110268

Device Name: Force Triad™ Electrosurgical Generator

Indications for Use:

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110268